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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,776	08/23/2000	John Burczak	DEX-0079	2610

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 10/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/622,776</b>	Applicant(s) <b>Burczak et al</b>
Examiner <b>Ungar</b>	Art Unit <b>1642</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Sep 3, 2002

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 10-12 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 10-12 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

6)  Other: \_\_\_\_\_

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1. The Amendment filed September 11, 2002 (Paper No. 8) in response to the Office Action of May 2, 2002 (Paper No. 6) is acknowledged and has been entered. Previously pending claims 1-3, 5-8, 13-15 have been canceled, claim 10 has been amended.. Claims 10-12 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

*New Grounds of Rejection*

*Claim Rejections - 35 USC § 112*

3. Claims 10-12 are rejected under 35 USC 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method of diagnosing ovarian or testicular cancer in a patient comprising obtaining a sample of biological fluid from a patient and detecting levels of PLA2 in the sample wherein elevated levels of PLA2 at least two standard deviations above levels of PLA2 determined in random healthy males or females in the sample are indicative of ovarian or testicular cancer, wherein the fluid is serum, wherein the assay is ELISA.

The specification teaches that PLA2 levels are known to be elevated in breast cancer patients (p. 2), gastric, pancreatic, bile duct, lung, liver, esophageal and uterine cancers as reported by Abe et al, Int. J. Cancer (Pred.Oncol), 1997, 74:245-250, IDS item (p. 3, lines 4-8). The specification further teaches that no patients with localized ovarian cancer had serum levels of PLA2 above 4.5 ng/ml (the cut-off

point for random normal males), 3 of 6 patients with localized testicular cancer had serum levels of PLA2 above 4.5 ng/ml, 26 of 36 patients with progressive ovarian cancer had serum levels of PLA2 above 4.5 ng/ml and 9 of 14 patients with progressive testicular cancer had serum levels of PLA2 above 4.5 ng/ml (Table 2, page 14). It is noted that no data for individual patients is reported and no information is provided as to how high above 4.5 ng/ml each of the PLA2 assays was found to be. However, the specification states that levels of PLA2, at least two standard deviations above levels of PLA2 determined in healthy males are indicative of ovarian or testicular cancer (p. 16, lines 6-9). One cannot extrapolate the teaching of the specification to the enablement of the claims because it is known in the art that the mean for PLA2 levels in normal healthy men is 4.85 ng/ml +/- 3.29 (see 5,747,264, col 9, lines 45-50, of record). Given that the Range of Variability is 6.58, it would appear that the standard deviation for the PLA2 level in normal healthy men is approximately 1 ng/ml, thus two standard deviations above the mean would be approximately 6.85 ng/ml. As reported in the specification, Abe et al specifically teach elevated PLA2 concentrations in serum for a variety of cancer types. A review of Figure 1 on page 247 of the reference clearly shows that 11 of the 31 serum samples tested from a variety of cancers showed concentrations above 6.85 ng/ml. Although the reference does not state specifically which samples tested that were at least two standard deviations above normal male control, it is not clear, if either ovarian or testicular cancer serum samples had been included in the assay and had shown levels above 2 standard deviations above normal male, how either ovarian or testicular cancers could be distinguished from the tested variety of tumor

types. Further, US Patent No. 5,747,264, of record, specifically teaches that patients with progressive prostate cancer, prostate cancer in remission, patients with stabilized prostate cancer, patients with prostatitis all assayed with at PLA2 concentrations in serum at least two standard deviations above normal male control (see columns 9 and 10). It is not clear, if either ovarian or testicular cancer serum samples had been included in the assay, how either ovarian or testicular cancers could be distinguished from the tested prostate cancer and prostatitis samples.

Finally, Yamashita et al (Clinica Chimica Acta, 1994, 228:91-99), of record, clearly demonstrates that 3 lung cancer samples, 7 breast cancer samples, 4 esophageal cancer samples, 9 colorectal cancer samples, 3 liver cancer samples, 5 bile duct cancer samples and two pancreatic cancer samples all assayed with PLA2 concentrations in serum at least two standard deviations above normal male control. It is not clear, if either ovarian or testicular cancer had been included in the assay, how either ovarian or testicular cancers could be distinguished from the these cancer samples. Further, the specification provides no information regarding the level of PLA2 concentration in bodily fluids of patients with either ovarian or testicular cancer. Although the specification teaches that the levels are greater than 4.5 ng/ml, there is no teaching that any of the samples tested was found to have concentrations of PLA2 greater than at least two standard deviations above normal control. The art of ovarian or testicular cancer diagnosis by assay of PLA2 in a bodily fluid is an undeveloped art. Although many cancer types have been assayed, there is no information in the art drawn to either ovarian or testicular cancer PLA2 levels in bodily fluids. Given the above, it cannot be predicted whether or which of the

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patients assayed would have either ovarian or testicular cancer wherein the PLA2 assayed was at least two standard deviations above normal control. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict that the invention will function as claimed with a reasonable expectation of success. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

4. Claims 10-12 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of "levels of PLA2 at least two standard deviations above levels of PLA2 determined in random healthy males or females" claimed in claim 10 has no clear support in the specification and the claims as originally filed. Applicant points to support for the newly added limitation on page 15, lines 25-32 and on page 16, lines 6-9. A review of the cited support reveals support for, on page 15, elevated PLA2 levels in bodily fluid being indicative of ovarian or testicular cancer in the patient and support for the percent of individuals positive for PLA2 being generally greater than random healthy males or females. A review of the cited support reveals support for, on page 15, PLA2 levels at least two standard deviations above levels of PLA2 determined in healthy males are indicative of ovarian or testicular cancer. The cited support is not persuasive because there is no suggestion of a cut-off point from random healthy females and no nexus between the at least two standard deviations recited drawn to random healthy males and any cut-off point for random

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healthy females. The subject matter claimed in claims 8-10 broadens the scope of the invention as originally disclosed in the specification.

5. All other objections and rejections recited in Paper No. 6 are withdrawn.
6. No claims allowed.
7. Applicant's amendment necessitated the new grounds of rejection.

Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1640.

  
Susan Ungar  
Primary Patent Examiner  
October 7, 2002